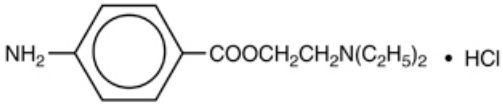
NOVOCAIN - procaine hydrochloride injection, solution
Hospira, Inc.

Local Anesthetic for Local Infiltration and Peripheral Nerve Block
THESE SOLUTIONS ARE NOT INTENDED FOR SPINAL OR EPIDURAL ANESTHESIA OR DENTAL USE
R_x only

DESCRIPTION

Procaine hydrochloride is benzoic acid, 4-amino-, 2-(diethylamino) ethyl ester, monohydrochloride, the ester of diethylaminoethanol and para-aminobenzoic acid, with the following structural formula:



It is a white crystalline, odorless powder that is freely soluble in water, but less soluble in alcohol and has a molecular weight of 272.78.

Composition of Available Solutions

Each mL contains	1% Ampul	1% Vial	2% Vial
Procaine hydrochloride	10 mg	10 mg	20 mg
Acetone sodium bisulfite	≤ 1 mg	≤ 2 mg	≤ 2 mg
Chlorobutanol	–	≤ 2.5 mg	≤ 2.5 mg

[Acetone sodium bisulfite is added as an antioxidant in all products, and chlorobutanol is added as an antimicrobial preservative in the multiple-dose vials.]

The solutions are made isotonic with sodium chloride and the pH is adjusted between 3 and 5.5 with sodium hydroxide and/or hydrochloric acid.
Procaine hydrochloride is related chemically and pharmacologically to the ester-type local anesthetics. It contains an ester linkage between the aromatic nucleus and the amino group.
NOVOCAIN is available as sterile solutions in concentrations of 1% and 2% for injection via local infiltration and peripheral nerve block.

CLINICAL PHARMACOLOGY

Local anesthetics block the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential.
In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of affected nerve fibers. Clinically, the order of loss of nerve function is as follows: pain, temperature, touch, proprioception, and skeletal muscle tone.
Procaine lacks topical anesthetic activity.
Systemic absorption of local anesthetics produces effects on the cardiovascular and central nervous systems. At blood concentrations achieved with normal therapeutic doses, changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal. However, toxic blood concentrations depress cardiac conduction and excitability, which may lead to atrioventricular block and ultimately to cardiac arrest. In addition, myocardial contractility is depressed and peripheral vasodilation occurs, leading to decreased cardiac output and arterial blood pressure.
Following systemic absorption, local anesthetics can produce central nervous system stimulation, depression, or both. Apparent central stimulation is manifested as restlessness, tremors and shivering, progressing to convulsions, followed by depression, and coma progressing ultimately to respiratory arrest. However, the local anesthetics have a primary depressant effect on the medulla and on higher centers. The depressed stage may occur without a prior excited stage.

Pharmacokinetics:
The rate of systemic absorption of local anesthetics is dependent upon the total dose and concentration of drug administered, the route of administration, the vascularity of the administration site, and the presence or absence of epinephrine in the anesthetic solution.
A dilute concentration of epinephrine (1:200,000 or 5 μg/mL) usually reduces the rate of absorption and plasma concentration of NOVOCAIN. It also will promote local hemostasis and increase the duration of anesthesia.
Onset of anesthesia with NOVOCAIN is rapid, the time of onset for sensory block ranging from about two to five minutes depending upon such factors as the anesthetic technique, the type of block, the concentration of the solution, and the individual patient. The degree of motor blockade produced is dependent on the concentration of the solution.

The duration of anesthesia also varies depending upon the technique and type of block, the concentration, and the individual. NOVOCAIN will normally provide anesthesia which is adequate for one hour.
Local anesthetics are bound to plasma proteins in varying degrees. Generally, the lower the plasma concentration of drug, the higher the percentage of drug bound to plasma.
Local anesthetics appear to cross the placenta by passive diffusion. The rate and degree of diffusion is governed by the degree of plasma protein binding, the degree of ionization, and the degree at lipid solubility. Fetal/maternal ratios of local anesthetics appear to be inversely related to the degree of plasma protein binding, because only the free, unbound drug is available for placental transfer. The extent of placental transfer is also determined by the degree of ionization and lipid solubility of the drug. Lipid, soluble nonionized drugs readily enter the fetalblood from the maternal circulation.
Depending upon the route of administration, local anesthetics are distributed to some extent to all body tissues, with high concentrations found in highly perfused organs such as the liver, lungs, heart, and brain.
Various pharmacokinetic parameters of the local anesthetics can be significantly altered by the presence of hepatic or renal disease, addition of epinephrine, factors affecting urinary pH, renal blood flow, the route of drug administration, and the age of the patient. The *in vitro* plasma half-life of NOVOCAIN in adults is 40 ± 9 seconds and in neonates 84 ± 30 seconds.
NOVOCAIN is readily absorbed following parenteral administration and is rapidly hydrolyzed by plasma cholinesterase to para-aminobenzoic acid and diethylaminoethanol.
The para-aminobenzoic acid metabolite inhibits the action of the sulfonamides. (See PRECAUTIONS.)
For NOVOCAIN, approximately 90% of the para-aminobenzoic acid metabolite and its conjugates and 33% of the diethylaminoethanol metabolite are recovered in the urine, while less than 2% of the administered dose is recovered unchanged in the urine.

INDICATIONS AND USAGE
NOVOCAIN is indicated for the production of local or regional analgesia and anesthesia by local infiltration and peripheral nerve block techniques.
The routes of administration and concentrations are: for local infiltration use 0.25% to 0.5% (via dilution) and for peripheral nerve blocks use 0.5% (via dilution), 1%, and 2%. (See DOSAGE AND ADMINISTRATION for additional information.)
Standard textbooks should be consulted to determine the accepted procedures and techniques for the administration of NOVOCAIN.

CONTRAINDICATIONS
NOVOCAIN is contraindicated in patients with a known hypersensitivity to procaine, drugs of a similar chemical configuration, or para-aminobenzoic acid or its derivatives.
It is also contraindicated in patients with a known hypersensitivity to other components of solutions of NOVOCAIN.

WARNINGS
Contains acetone sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.
LOCAL ANESTHETICS SHOULD ONLY BE EMPLOYED BY CLINICIANS WHO ARE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF DOSE-RELATED TOXICITY AND OTHER ACUTE EMERGENCIES WHICH MIGHT ARISE FROM THE BLOCK TO BE EMPLOYED, AND THEN ONLY AFTER INSURING THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY RESUSCITATIVE EQUIPMENT, AND THE PERSONNEL RESOURCES NEEDED FOR PROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES. (See also ADVERSE REACTIONS and PRECAUTIONS.) DELAY IN PROPER MANAGEMENT OF DOSE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE, AND/OR ALTERED SENSITIVITY MAY LEAD TO THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST, AND, POSSIBLY, DEATH.
It is essential that aspiration for blood or cerebrospinal fluid, where applicable, be done prior to injecting any local anesthetic, both the original dose and all subsequent doses, to avoid intravascular or subarachnoid injection. However, a negative aspiration does not ensure against an intravascular or subarachnoid injection.
Reactions resulting in fatality have occurred on rare occasions with the use of local anesthetics, even in the absence of a history of hypersensitivity. Large doses of local anesthetics should not be used in patients with heartblock.
NOVOCAIN with epinephrine or other vasopressors should not be used concomitantly with ergot-type oxytocic drugs, because a severe persistent hypertension may occur. Likewise, solutions of NOVOCAIN containing a vasoconstrictor, such as epinephrine, should be used with extreme caution in patients receiving monoamine oxidase inhibitors (MAOI) or antidepressants of the triptyline or imipramine types, because severe prolonged hypertension or disturbances of cardiac rhythm may occur.
Local anesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.
Mixing or the prior or intercurrent use of any local anesthetic with NOVOCAIN cannot be recommended because of insufficient data on the clinical use of such mixtures.

PRECAUTIONS

General:

The safety and effectiveness of local anesthetics depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use. (See WARNINGS and ADVERSE REACTIONS.) During major regional nerve blocks, the patient should have IV fluids running via an indwelling catheter to assure a functioning intravenous pathway. The lowest dosage of local anesthetic that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Injections should be made slowly, with frequent aspirations before and during the injection to avoid intravascular injection. Current opinion favors fractional administration with constant attention to the patient, rather than rapid bolus injection. Syringe aspirations should also be performed before and during each supplemental injection in continuous (intermittent) catheter techniques. An intravascular injection is still possible even if aspirations for blood are negative.

Injection of repeated doses of local anesthetics may cause significant increases in plasma levels with each repeated dose due to slow accumulation of the drug or its metabolites or to slow metabolic degradation. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients and acutely ill patients should be given reduced doses commensurate with their age and physical status. Local anesthetics should also be used with caution in patients with severe disturbances of cardiac rhythm, shock, heartblock, or hypotension.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be performed after each local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, incoherent speech, light-headedness, numbness, and tingling of the mouth and lips, metallic taste, tinnitus, dizziness, blurred vision, tremors, twitching, depression, or drowsiness may be early warning signs of central nervous system toxicity.

Local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully circumscribed quantities in areas of the body supplied by end arteries, or those areas having otherwise compromised blood supply such as digits, nose, external ear, penis. Patients with peripheral vascular disease and hypertensive vascular disease may exhibit an exaggerated vasoconstrictor response. Ischemic injury or necrosis may result.

NOVOCAIN should be used with caution in patients with known allergies and sensitivities. A thorough history of the patient's prior experience with NOVOCAIN or other local anesthetics as well as concomitant or recent drug use should be taken. (See CONTRAINDICATIONS and WARNINGS.)

Because ester-type local anesthetics such as NOVOCAIN are hydrolyzed by plasma cholinesterase produced by the liver and excreted by the kidneys, these drugs, especially repeat doses, should be used cautiously in patients with hepatic disease. Because of their inability to metabolize local anesthetics normally, patients with severe hepatic disease are at a greater risk of developing toxic plasma concentrations. Local anesthetics should also be used with caution in patients with impaired cardiovascular function because they may be less able to compensate for functional changes associated with the prolongation of AV conduction produced by these drugs.

Serious dose-related cardiac arrhythmias may occur if preparations containing a vasoconstrictor such as epinephrine are employed in patients during or following the administration of potent inhalation anesthetics. In deciding whether to use these products concurrently in the same patient, the combined action of both agents upon the myocardium, the concentration and volume of vasoconstrictor used, and the time since injection, when applicable, should be taken into account.

Many drugs used during the conduction of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Because it is not known whether ester-type local anesthetics may trigger this reaction and because the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure, and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s), and institution of treatment, including oxygen therapy, indicated supportive measures, and dantrolene. (Consult dantrolene sodium intravenous package insert before using.)

Use in Head and Neck Area:

Small doses of local anesthetics injected into the head and neck area may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported.

These reactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these blocks should have their circulation and respiration monitored and be constantly observed. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded.

Information for Patients:

When appropriate, patients should be informed, in advance, that they may experience temporary loss of sensation and motor activity following proper administration of regional anesthesia. Also, when appropriate, the physician should discuss other information including adverse reactions in the package insert.

Clinically Significant Drug Interactions:
The administration of local anesthetic solutions containing epinephrine or norepinephrine to patients receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe, prolonged hypertension. Concurrent use of these agents should generally be avoided. In situations when concurrent therapy is necessary, careful patient monitoring is essential.
Concurrent administration of vasopressor drugs and of ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents.
Phenothiazines and butyrophenones may reduce or reverse the pressor effect of epinephrine.
The clinical observation has been made that despite adequate sulfonamide therapy, local infections have occurred in areas infiltrated with procaine hydrochloride prior to diagnostic punctures and drainage procedures. Therefore, NOVOCAIN should not be used in any condition in which a sulfonamide drug is being employed since para-aminobenzoic acid inhibits the action of the sulfonamide.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:
Long-term studies in animals of most local anesthetics, including procaine hydrochloride, to evaluate the carcinogenic potential have not been conducted. Mutagenic potential or the effect on fertility have not been determined. There is no evidence from human data that NOVOCAIN may be carcinogenic, or mutagenic, or that it impairs fertility.

Pregnancy Category C:
Animal reproduction studies have not been conducted with NOVOCAIN. It is not known whether procaine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. NOVOCAIN should be given to a pregnant woman only if clearly needed and the potential benefits outweigh the risk. This does not exclude the use of procaine hydrochloride at term for obstetrical anesthesia or analgesia. (See *Labor and Delivery*.)

Labor and Delivery:
Local anesthetics rapidly cross the placenta, and when used for paracervical or pudendal block anesthesia, can cause varying degrees of maternal, fetal, and neonatal toxicity. (See CLINICAL PHARMACOLOGY.) The incidence and degree of toxicity depend upon the procedure performed, the type and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus, and neonate involve alterations of the central nervous system, peripheral vascular tone, and cardiac function.
Maternal hypotension has resulted from regional anesthesia. Local anesthetics produce vasodilation by blocking sympathetic nerves. Elevating the patient’s legs and positioning her on her left side will help prevent decreases in blood pressure. The fetal heart rate also should be monitored continuously and electronic fetal monitoring is highly advisable.
Paracervical or pudendal anesthesia may alter the forces at parturition through changes in uterine contractility or maternal expulsive efforts. In one study, paracervical block anesthesia was associated with a decrease in the mean duration of first stage labor and facilitation of cervical dilation. The use of obstetrical anesthesia may increase the need for forceps assistance.
The use of some local anesthetic drug products during labor and delivery may be followed by diminished muscle strength and tone for the first day or two of life. The long-term significance of these observations is unknown.
Fetal bradycardia which frequently follows paracervical block may be indicative of high fetal blood concentrations of procaine with resultant fetal acidosis. Fetal heart rate should be monitored prior to and during paracervical block. Added risk appears to be present in prematurity, toxemia of pregnancy, and fetal distress. The physician should weigh the considering paracervical block in these conditions. Careful adherence to recommended dosage is of the utmost importance in paracervical block. Failure to achieve adequate analgesia with these doses should arouse suspicion of intravascular or fetal injection.
Cases compatible with unintended fetal intracranial injection of local anesthetic solution have been reported following intended paracervical or pudendal block or both. Babies so affected present with unexplained neonatal depression at birth, which correlates with high local anesthetic serum levels, and usually manifest seizures within six hours. Prompt use of supportive measures combined with forced urinary excretion of the local anesthetic has been used successfully to manage this complication.
Case reports of maternal convulsions and cardiovascular collapse following use of some local anesthetics for paracervical block in early pregnancy (as anesthesia for elective abortion) suggest that systemic absorption under these circumstances may be rapid. The recommended maximum dose of the local anesthetic should not be exceeded. Injection should be made slowly and with frequent aspiration. Allow a five-minute interval between sides.
It is extremely important to avoid aortocaval compression by the gravid uterus during administration of regional block to parturients. To do this, the patient must be maintained in the left lateral decubitus position or a blanket roll or sandbag may be placed beneath the right hip and the gravid uterus displaced to the left.

Nursing Mothers:
It is not known whether local anesthetic drugs are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when local anesthetics are administered to a nursing woman.

Pediatric Use:
(See DOSAGE AND ADMINISTRATION.)

ADVERSE REACTIONS

Reactions to procaine are characteristic of those associated with other ester-type local anesthetics. A major cause of adverse reactions to this group of drugs is excessive plasma levels which may be due to overdosage, rapid absorption, inadvertent intravascular injection, or slow metabolic degradation.

A small number of reactions may result from hypersensitivity, idiosyncrasy, or diminished tolerance to normal dosage.

Systemic:

The most commonly encountered acute adverse experiences which demand immediate countermeasures are related to the central nervous system and the cardiovascular system. These adverse experiences are generally dose related and due to high plasma levels which may result from overdosage, rapid absorption from the injection site, diminished tolerance, or from unintentional intravascular injection of the local anesthetic solution. In addition to systemic dose-related toxicity, unintentional subarachnoid injection of drug during the intended performance of nerve blocks near the vertebral column (especially in the head and neck region), may result in underventilation or apnea ("Total or High Spinal"). Factors influencing plasma protein binding, such as acidosis, systemic diseases which alter protein production, or competition of other drugs for protein binding sites may diminish individual tolerance.

Plasma cholinesterase deficiency may also account for diminished tolerance to ester-type local anesthetics.

Central Nervous System Reactions:

These are characterized by excitation and/or depression. Restlessness, anxiety, dizziness, tinnitus, blurred vision, or tremors may occur, possibly proceeding to convulsions. However, excitement may be transient or absent, with depression being the first manifestation of an adverse reaction. This may quickly be followed by drowsiness merging into unconsciousness and respiratory arrest.

The incidence of convulsions associated with the use of local anesthetics varies with the procedure used and the total dose administered.

Cardiovascular Reactions:

High doses or inadvertent intravascular injection may lead to high plasma levels and related depression of the myocardium, decreased cardiac output, heartblock, hypotension (or sometimes hypertension), bradycardia, ventricular arrhythmias, and cardiac arrest. (See WARNINGS, PRECAUTIONS, and OVERDOSAGE sections.)

Allergic:

Allergic-type reactions are rare and may occur as a result of sensitivity to the local anesthetic or to other formulation ingredients, such as the antimicrobial preservative chlorobutanol contained in multiple-dose vials. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and, possibly, anaphylactoid-like symptomatology (including severe hypotension). Cross sensitivity among members of the ester-type local anesthetic group has been reported. The usefulness of screening for sensitivity has not been definitely established.

Neurologic:

The incidences of adverse neurologic reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered, and are also dependent upon the particular drug used, the route of administration, and the physical status of the patient. Many of these effects may be related to local anesthetic techniques, with or without a contribution from the drug.

OVERDOSAGE

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics or to unintended subarachnoid injection of local anesthetic solution. (See ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS.)

Management of Local Anesthetic Emergencies:

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs, and the patient's state of consciousness after each local anesthetic injection. At the first sign of change, oxygen should be administered.

The first step in the management of systemic toxic reactions, as well as underventilation or apnea due to unintentional subarachnoid injection of drug solution, consists of immediate attention to the establishment and maintenance of a patent airway, and effective assisted or controlled ventilation with 100% oxygen with a delivery system capable of permitting immediate positive airway pressure by mask. This may prevent convulsions if they have not already occurred.

If necessary, use drugs to control the convulsions. A 50 mg to 100 mg bolus IV injection of succinylcholine will paralyze the patient without depressing the central nervous or cardiovascular systems and facilitate ventilation. A bolus IV dose of 5 mg to 10 mg of diazepam or 50 mg to 100 mg of thiopental will permit ventilation and counteract central nervous system stimulation, but these drugs also depress central nervous system, respiratory and cardiac function, add to postictal depression, and may result in apnea. Intravenous barbiturates, anticonvulsant agents, or muscle relaxants should only be administered by those familiar with their use. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should he evaluated. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor dictated by the clinical situation (such as ephedrine or epinephrine to enhance myocardial contractile force).

Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

Recent clinical data from patients experiencing local anesthetic-induced convulsions demonstrated rapid development of hypoxia, hypercarbia, and acidosis within a minute of the onset of convulsions. These observations suggest that oxygen consumption and carbon dioxide production are greatly increased during local anesthetic convulsions, and emphasize the importance of immediate and effective ventilation with oxygen which may avoid cardiac arrest.

If not treated immediately, convulsions with simultaneous hypoxia, hypercarbia, and acidosis plus myocardial depression from the direct effects of the local anesthetic may result in cardiac arrhythmias, bradycardia, asystole, ventricular fibrillation, or cardiac arrest. Respiratory abnormalities, including apnea, may occur. Underventilation or apnea due to unintentional subarachnoid injection of local anesthetic solution may produce these same signs and also lead to cardiac arrest if ventilatory support is not instituted. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted and maintained for a prolonged period if necessary. Recovery has been reported after prolonged resuscitative efforts.

The supine position is dangerous in pregnant women at term because of aortocaval compression by the gravid uterus. Therefore, during treatment of systemic toxicity, maternal hypotension, or fetal bradycardia following regional block, the parturient should be maintained in the left lateral decubitus position if possible, or manual displacement of the uterus off the great vessels be accomplished.

The intravenous and subcutaneous and intraperitoneal LD_{50} of procaine hydrochloride in mice is 46 mg/kg to 80 mg/kg and 400 mg/kg and 200 mg/kg respectively.

DOSAGE AND ADMINISTRATION

The dose of any local anesthetic administered varies with the anesthetic procedure, the area to be anesthetized, the vascularity of the tissues, the number of neuronal segments to be blocked, the depth of anesthesia and degree of muscle relaxation required, the duration of anesthesia desired, individual tolerance, and the physical condition of the patient. The smallest dose and concentration required to produce the desired result should be administered. Dosages of NOVOCAIN should be reduced for elderly and debilitated patients and patients with cardiac and/or liver disease. The rapid injection of a large volume of local anesthetic solution should be avoided and fractional doses should be used when feasible.

For specific techniques and procedures, refer to standard textbooks.

For infiltration anesthesia, 0.25% or 0.5% solution; 350 mg to 600 mg is generally considered to be a single safe total dose. To prepare 60 mL of a 0.5% solution (5 mg/mL), dilute 30 mL of the 1% solution with 30 mL sodium chloride injection 0.9%. To prepare 60 mL of a 0.25% solution (2.5 mg/mL), dilute 15 mL of the 1% solution with 45 mL sodium chloride injection 0.9%. An anesthetic solution of 0.5 mL to 1 mL of epinephrine 1:1,000 per 100 mL may be added for vasoconstrictive effect (1:200,000 to 1:100,000). (See WARNINGS and PRECAUTIONS.)

For peripheral nerve block, 0.5% solution (up to 200 mL), 1% solution (up to 100 mL), or 2% solution (up to 50 mL). The use of the 2% solution should usually be limited to cases requiring a small volume of anesthetic solution (10 mL to 25 mL). An anesthetic solution of 0.5 mL to 1 mL of epinephrine 1:1,000 per 100 mL may be added for vasoconstrictive effect (1:200,000 to 1:100,000). (See WARNINGS and PRECAUTIONS.)

THE USUAL TOTAL DOSE DURING ONE TREATMENT SHOULD NOT EXCEED 1,000 MG.

This product should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not use solutions if crystals, cloudiness, or discoloration is observed. Examine solution carefully before use. Reautoclaving increases likelihood of crystal formation. Solutions which are discolored or which contain particulate matter should not be administered.

Unused portions of solutions not containing preservatives should be discarded.

Pediatric Use:

In pediatric patients 15 mg/kg of a 0.5% solution for local infiltration is the maximum recommended dose.

HOW SUPPLIED

Single-dose containers and multiple-dose containers of NOVOCAIN may be sterilized by autoclaving at 15-pound pressure, 121°C (250°F) for 15 minutes. Do not use solutions if crystals, cloudiness, or discoloration is observed. Examine solution carefully before use. Reautoclaving increases likelihood of crystal formation. Do not administer solutions which are discolored or which contain particulate matter. Protect solutions from light.

Unused portions of solutions not containing preservatives, i.e., those supplied in ampuls, should be discarded following initial use.

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List	Container	Concentration	Fill	Quantity
1808	Uni-Amp® unit dose pak	1 %	2 mL	25
1808	Single-Dose Ampuls	1 %	6 mL	50
1824	Multiple-Dose Vials	1 %	30 mL	1

1825	Multiple-Dose Vials	2 %	30 mL	1

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